

hole within the top surface of the cartridge. The cartridge may include more than one input port, so that a fluid, or fluids, may be added at different time points and/or locations within the cartridge. It is to be understood that a fluid-tight seal is generally formed between each said input port of the cartridge and a feature, such as a valve or tubing within the reader, which may be connected to the reservoir fluid.

[0018] Desirably, said channel(s) in the cartridge also comprise one or more fluid stop features, which are designed to prevent the sample and/or other fluids from passing through the stop feature, by virtue of capillary action alone. That is, the sample or any other fluid may be actively forced past said stop feature(s) by a force, such as that applied by a pump/pumps provided by the reader. A preferred stop feature is a hydrophobic material (e.g. printable conductive or non conductive inks) or a process or material that changes the surface properties of a channel surface therefore creating a hydrophilic/hydrophobic differential (e.g. by way of laser ablation, surface scoring, surface material removal, evaporated metallic materials etc), which is designed to abut/be a wall feature or is coated on a wall of the channel. In the embodiment where the channels are formed by virtue of three substrates being sandwiched together thereby forming the channels, the hydrophobic material may be applied to the top and/or bottom substrates, such that when the three substrates are sandwiched together, the hydrophobic stop material forms a feature on the top and/or bottom surface of said channel.

[0019] It is also preferred that a stop feature be located upstream of the sink feature, in order that the sample, upon initial application, does not flow into the sink feature. Only when a force, such as provided by way of a pump/pumps, within the reader is applied, can fluid pass the stop feature upstream of the sink feature and hence allow fluid to pass into the sink. The fluid outlet sink is designed to be a void area of the cartridge into which spent fluid or fluid which is not required or deemed undesirable, may be evacuated. For example, whole blood contains many proteins and other agents which can interfere with assay reactions and/or detection of captured analyte, by way of fluorescence detection, for example. The present invention allows the initial binding of any analyte to be carried out within the sample of whole blood, but all or substantially all of the unbound material can subsequently be evacuated to the sink feature, enabling further reactions and/or detection to be carried out in a defined media or buffer.

[0020] As well as the microfluidic channel(s), the cartridge of the present invention may comprise one or more electrode features which contact with the channel and hence the sample once introduced into the cartridge. The electrodes are designed to contact electrical contacts within the reader, enabling a variety of readings to be taken, where appropriate. For example, one or more electrodes in the cartridge may be designed to detect correct loading of the cartridge and the reader may signal to the user whether or not the cartridge has a) been correctly inserted into the reader and/or the sample loaded into the cartridge correctly. The electrode(s) may also carry out one or more electrical measurements on the sample itself. For example, when the sample is a sample of whole blood, the electrode(s) may conduct a hematocrit measurement of the sample, which may be important in determining an accurate concentration of the analyte to be detected. Conductivity and/or impedance measurements may be determined depending on the sample being studied. Thus, the cartridges of the present invention may not only detect

whether or not an analyte is present in a sample by way of binding any analyte, but electrical measurements on the sample may also be conducted.

[0021] The sample to be applied to the cartridge may be any suitable fluid sample. It may for example be a sample of fluid obtained from a subject, such as a whole blood, plasma, saliva, semen, sweat, serum, menses, amniotic fluid, tears, a tissue swab, urine, cerebrospinal fluid, mucous and the like. It is to be appreciated that the assay systems of the present invention may be applied in the human health area, including large and growing IVD markets (e.g. cancer, cardiology, and infectious disease). The assays may also be used to test drugs and drug action. However, the system may also be applied in environmental settings where it is desirable to detect, for example toxic agents or infectious agents such as bacteria or viruses. Thus, samples from rivers or lakes or swabs from solid surfaces may be taken in order to obtain a fluid sample for providing to the cartridge. The assay systems may also be utilised for veterinary applications. Essentially any assay in which a sample can be provided in a fluid form may be utilised in the present invention.

[0022] The sample may, for instance, include materials obtained directly from a source, such as a sample of whole blood, as well as materials pretreated using techniques, such as filtration, precipitation, dilution, distillation, mixing, concentration, inactivation of interfering agents, etc. These steps may be carried out prior to the sample being introduced to the cartridge or may be carried out by the cartridge itself.

[0023] The sample may be introduced prior to the cartridge being inserted into the reader or after the cartridge has been inserted into the reader. The cartridge may be so designed that the sample is introduced by way of capillary action, or by virtue of a seal being formed between an input port of the cartridge and the reader, the sample may be actively drawn into the cartridge by way of air being drawn through the microfluidic channel(s) by a pump/pumps in the reader, such as a pump/pumps.

[0024] The analyte to be detected can be any desired analyte and may include proteins, peptides, antibodies, nucleic acid, microorganisms (such as bacteria and viruses), chemical agents, toxins, pharmaceuticals, metabolites, cellular moieties and the like. For example, the present system may be adapted to detect any type of analyte that can bind a suitable binding agent. The binding agent may be any suitable agent which is able to bind specifically to the analyte to be detected. For example, if the analyte is a protein or peptide, the binding agent may be a receptor or antibody which is capable of specifically binding to the protein/peptide. Conversely an antibody may be bound by a protein/peptide which the antibody is designed to specifically bind to. Nucleic acids may be bound by other nucleic acids which are capable of specifically hybridising to the analyte nucleic acid. Microorganisms may be bound by antibodies which specifically bind to proteins on the surface of the microorganism. Chemical agents, toxins, pharmaceuticals, metabolites may be bound by chemical moieties which are capable of reacting or binding to the aforementioned chemical analytes via appropriate bonding reactions, or affinities. Many types of binding techniques are well known to those of skill in the art.

[0025] Moreover, the binding agent may be an enzyme or an enzyme substrate. For example analytes such as glucose through well described enzymatic methodologies may be detected, for example the reaction product formed following the enzyme reacting with the glucose may be detected by